



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,086	07/31/2006	Tadashi Yoneda	Q79826	4024
23373 7590 12/11/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER HA, JULIE	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 12/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,086

Applicant(s)

YONEDA, TADASHI

Examiner

JULIE HA

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 15, 16 and 18 is/are rejected.
- 7) ☒ Claim(s) 20-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Amendment after Non-final rejection filed August 29, 2008 is acknowledged. Claims 14 and 17 have been cancelled and new claims 20-22 are added. Applicant elected without traverse Group II (claims 11-18) and elected species wherein R is isoalkyl group having 11 carbon atoms, X is leucine, polyhydric alcohol is water and glycerin, tocopherol compound is g-tocopherol and oil component is polyoxyethylene (20) glyceryl triostearate and glycerin tri-2-ethylhexanoate in the reply filed on March 20, 2008. The restriction was considered to be proper and made FINAL in the previous office action. Claims 1-10 and 19 remain withdrawn from further consideration, as being drawn to nonelected invention. Claims 11-13, 15-16, 18 and 20-22 are examined on the merits in this office action.

Priority

1. Applicant indicates that on the Office Action Summary, the Examiner has acknowledged Applicant's claim for priority, and has marked box 12a) but not box 12a)3. Applicant requested that the Examiner make an appropriate indication in the next communication from the PTO.
2. The Office Action Summary (PTO 326) has been corrected to indicate that copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

Withdrawn Rejections

3. Rejection of claims 11-13, 15-16 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn in view of Applicant's amendment to the claims.
4. Rejection of claims 11-13, 15-16 and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description is hereby withdrawn in view of Applicant's amendment to the claims.
5. Rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Kovacs et al (US Patent No. 5,583,105) as evidenced by Mishra et al (US Patent No. 6,284,268) is hereby withdrawn in view of Applicant's amendment to the claims.

Maintained Rejection

35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoneda et al (WO 03/013446 A1) in view of Goodman et al (U.S. Patent 4,883,659).

9. Yoneda et al teach an oily thickened gel-like which contains an anionic surfactant, water and/or polyhydric alcohol and oily ingredient; an emulsified composition obtained by adding water to the oily thickened gel-like composition; a cosmetic composition containing the oily thickened gel-like composition or the emulsified composition, and the anionic surfactant has a lipopeptide structure (see abstract). The reference further teaches that as a result of extensive investigations to attain the above-described object, the present inventors have found that an oily thickened gel-like composition comprising an anionic surfactant, water and/or polyhydric alcohol, and an oily ingredient can be prepared. In addition, when this oily thickened gel-like composition is diluted with water, a stable emulsified composition can be obtained (see p. 4, lines 12-20). The reference further teaches the same surfactin compound formula (1) as the instant application. The reference teaches 0.01 to 45% anionic surfactant, water and/or polyhydric alcohol in an amount of 0.01 to 43%, oily ingredient in an amount of 1 to 99%...salt of surfactin and/or salt of the homologue of the sodium surfactin (see pp. 5-6), meeting the limitations of claims 13-16. The reference teaches that the liquid oil is one or more liquid oils such as glycerol tri(2-ethylhexanoate) (see p. 7, lines 10-13), one of the elected species of oil component. The reference further teaches that an antioxidant and a perfume can also be blended in the oily thickened gel-like composition...examples of the antioxidant which can be used include, tocopherol, tocopherol acetate, vitamin As such as retinoic acid, retinoic acid

ester, retinol and retinoid (see pp. 16-17). The difference between the reference and the instant claims is that the reference does not teach the % anionic surfactant having a lipopeptide (0.01 to 5%), water and/or polyhydric alcohol (from 0.01 to 70%), oil component (30 to 99%), and tocopherol (0.01 to 2%).

10. Goodman et al teach that a skin treatment preparation (cosmetic as a film on the epidermal surface) that includes the addition of antioxidants and stabilizers, including tocopherol (or acetate) (see column 11, lines 20-25). The reference further teaches that the cosmetic formulations allow the inclusion of a variety of moisturizers/emollients other than the alcohols and surfactants above, such as anionic surfactants such as sodium lauryl sulfate (see column 10, line 51).

11. However, it would have been obvious to one of ordinary skill in the art to optimize the % concentrations of each component to arrive at an optimal composition. One of ordinary skill in the art would have been motivated to optimize the % concentrations of each component, because the optimized composition would be most effective and would have the best storage conditions, and would have been motivated to add stabilizers such as tocopherol, since the Yoneda reference teaches that antioxidants may be added to the formulation. Furthermore, it is well known in the art that antioxidants, such as tocopherol are used as aid for stabilization of the beneficial agent against degradation such as oxidation (see Goodman et al). Therefore, it would have been obvious to one of ordinary skill in the art to add in the tocopherol (antioxidant) to stabilize the formulation. Furthermore, the MPEP states the following: Generally, differences in concentration or temperature will not support the patentability of subject

matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). There is a reasonable expectation of success, since the normal desire of scientists are to improve upon what is already generally known with routine optimization. The optimization of

different component's concentration is deemed merely a matter of judicious selection and routine optimization that is well within the purview of skilled artisan. Therefore, the instant claims are unpatentable over the cited prior arts.

Response to Applicant's Arguments

12. Applicant argues that "Applicant submits that storage stability has a different meaning in the present application...and Applicant has amended claim 11 to recite that the storage stability comprises preventing separation of the composition." Applicant further argues that "Goodman et al disclose the storage stability against degradation such as oxidation, while storage stability in the present invention includes preventing separation of the composition." Furthermore, Applicant argues that "neither Yoneda nor Goodman teaches or suggests adding tocopherol compound in order to improve storage stability involving preventing separation of the composition. Further, it is submitted that claim 12 is additionally unobvious since the amount of tocopherol used in Yoneda is not disclosed." Additionally, Applicant argues that "the present invention provides unexpectedly superior results with respect to providing storage stability, including preventing separation, as can be seen from a comparison of the results of the Examples on page 24 in the specification with the corresponding Comparative Examples on page 25 in the specification."

13. Applicant's arguments have been fully considered but have not been found persuasive. Reasons for obviousness rejection can be completely different than instant application. Yoneda reference teaches all of the components claimed in the instant

claim 11 and suggests adding tocopherol. Goodman reference teaches that tocopherol is known as antioxidants and stabilizers, and tocopherol is useful for storage stability against degradation such as oxidation. Yoneda reference does not teach the specified % ranges of the components as the instant application. However, it would have been obvious for one of ordinary skill in the art to optimize the % concentrations of each component to arrive at an optimal composition that was most stable. Further, since the components of the composition are added up to 100%, it would have been obvious to one of ordinary skill in the art to optimize the % concentration of the tocopherol used for stabilizing the composition. One of ordinary skill in the art would have been motivated to optimize the % concentrations of the components, since it is the normal desire of a scientist to improve upon what is already known, and this provides motivation to optimize the concentration of components in a composition through routine experimentation.

In regards to Applicant's argument that "the present invention provides unexpectedly superior results with respect to providing storage stability," this is not found persuasive. According to MPEP 716.02 (a), a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). In the instant case, Applicant needs to present a side by side comparison between the claimed

invention and the closest art to show the allegedly surprising results, mere argument or allegation is insufficient to overcome the obviousness rejection.

In response to applicant's argument that "Applicant submits that storage stability has a different meaning in the present application...and Applicant has amended claim 11 to recite that the storage stability comprises preventing separation of the composition", the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). All prior arts combined have all of active method steps of instant claims. Since all of active method steps are present in the prior arts, the composition mechanistically would have the stabilizing property (i.e., the storage stability would comprise stabilization against separation of composition). Therefore, the combined components and active method steps of the prior art would necessarily be present because the prior arts teach all of the active steps with motivation to add in tocopherol for stabilization. A composition having all of the components would necessarily have the same properties. Therefore, the rejection is maintained.

Conclusion

14. Claims 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JULIE HA** whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/J. H./
Examiner, Art Unit 1654